UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,602	08/22/2003	Jun-Jei Sheu	2846-0259P	8573

2292 7590 05/25/2006

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,602	SHEU ET AL.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-13, 15, and 16 in the reply filed on April 24, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, claims 1-13, 15, and 16 will be examined.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Taiwan is not a country.

Specification

3. The amendment filed on August 22, 2003 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material "which is herein incorporated by reference" which is not supported by the original disclosure because the original filed specification does not required to incorporate Patent Application No. 2002-294229 filed in Japan on August 30, 2002 by reference.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

4. Claim 1 is objected to because of the following informalities: "intermediate solution" in line 6 should be "the intermediate solution".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Enablement

Claims 1-13, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also

stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to show that the method recited in claim 1 can be performed using any kind of intermediate solution with any kind of concentration so that the intermediate solution increases solubility between the first mixture and the second mixture, there is no predictability whether the method recited in claim 1 can be performed using any kind of intermediate solution with any kind of concentration.

Claims 1-13, 15, and 16 are directed to a method for mixing nucleic acid with a water insoluble medium and application thereof using any kind of intermediate solution with any kind of concentration so that the intermediate solution increases solubility between the first mixture and the second mixture. The specification does not provide a guidance to show that the method recited in claim 1 can be performed using any kind of intermediate solution so that the intermediate solution increases solubility between the first mixture and the second mixture. First, since claim 1 does not limit that intermediate solution is an organic solvent, when the intermediate solution is a water-soluble solution, a first solvent is a water-soluble solution, and a second solvent is an organic solvent, the intermediate solution cannot increase solubility between the first mixture and the second mixture. Second, even through intermediate solution is assumed as an organic solvent, a first solvent is a water-soluble solution, and a second solvent is an organic solvent, not all organic solvent such as phenol can increase solubility between the first mixture and the second mixture because phenol and water cannot form a one phase solution. Third, even through the intermediate solution is assumed as an organic solvent, a first solvent is a

water-soluble solution, and a second solvent is an organic solvent, since claim 1 does not limit that the concentration of the intermediate solution, not all organic solvent can be used to add into the first mixture so that the first mixture having the intermediate solution can increase solubility between the first mixture and the second mixture. For example, 75% ethanol cannot be used as an intermediate solution to increase solubility between the first mixture and the second mixture when a first solvent is a water-soluble solution and a second solvent is an organic solvent because nucleic acid in the first mixture will be precipitated by 75% ethanol. Therefore, it is unclear how to perform the method recited in claim 1 using any kind of intermediate solution so that the intermediate solution increases solubility between the first mixture and the second mixture.

With above unpredictable factor, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. The undue experimentation at least includes to test whether the method recited in claim 1 can be performed using any kind of intermediate solution with any kind of concentration.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-13, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is rejected as vague and indefinite because it is unclear how the intermediate solution can increase solubility between the first mixture and the second

mixture. For example, since claim 1 does not limit intermediate solution as an organic solvent, when intermediate solution is a water-soluble solution, a first solvent is a water-soluble solution, and a second solvent is an organic solvent, the intermediate solution cannot increase solubility between the first mixture and the second mixture. Furthermore, since claim 1 does not limit a first solvent as a water-soluble solution when intermediate solution is a water-soluble solution, a first solvent is an organic solvent, and a second solvent is an organic solvent, the intermediate solution cannot increase solubility between the first mixture and the second mixture. Please clarify.

10. Claim 3 is rejected as vague and indefinite. Since there is no definition for "water-insoluble medium" in the specification, water-insoluble medium is considered as 100% water insoluble. However, polycarbonate has water absorption from 0.15% to 0.35% (see page 5 of the attachment for polycarbonate). Please clarify.

11. Claim 9 is rejected as vague and indefinite because it is unclear what means that the intermediate solution is added to a final concentration of between 5 and 50% of the water-insoluble medium because, according to claim 1, intermediate solution is added to the first mixture and the third mixture contains the intermediate solution and there is no relationship between the intermediate solution and the water-insoluble medium. Please clarify.

12. Claim 16 is rejected as vague and indefinite. Since the claim does not limit the source of liquid article or substance and it is known that not any kind of liquid article or substance can bind to nucleic acid, it is unclear how to labeling liquid article or substance with the third mixture containing said nucleic acid. Please clarify.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-5, 7, 8, 10, 12, 13, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheu *et al.,* (US 2002/0187263 A1, filed on April 9, 2002)

The applied reference has a common inventor, Jue-Jei Sheu, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 1 and 10, Sheu *et al.,* teach adding intermediate solution (ie., solution having 70% ethanol and equal amount of acetone) to the first mixture (ie., a solution containing human white blood cell DNA) and mixing the first mixture having intermediate solution (ie., the DNA solution having 70% ethanol and equal amount of acetone) with the second mixture (ie., polycarbonate/chloroform solution) to form a third mixture wherein the medium (ie., polycarbonate) is inert medium and is not deteriorative to nucleic acid and wherein the intermediate solution (ie., an organic solvent:70% ethanol and equal amount of acetone) increases solubility between the first mixture (ie., a water

soluble solution) and the second mixture (ie., an organic solvent: polycarbonate /chloroform solution) (see page 2, [0015] and [0016]). Since Sheu *et al.,* teach to extract DNA from human white blood cell (page 2, [0015]), Sheu *et al.,* must dissolve nucleic acid in a first solvent to form a first mixture as recited in claim 1 wherein the first solvent comprises a water-soluble solution as recited in claim 10. Since Sheu *et al.,* teach that solution having 70% ethanol and equal amount of acetone is made from 95% ethanol and acetone while and polycarbonate /chloroform solution is made from polycarbonate and chloroform (see page 2, [0015] and [0016]), Sheu *et al.,* must disclose dissolving a water-insoluble medium (ie., polycarbonate) in a second solvent (ie., chloroform) to form a second mixture as recited in claim 1.

Regarding claims 2 and 3, Sheu *et al.,* teach that the water-insoluble medium comprises a polymeric substance such as polycarbonate (see page 2, [0015] and [0016]).

Regarding claims 4 and 5, Sheu *et al.,* teach that the second solvent comprises an organic solvent such as chloroform (see page 2, [0015] and [0016]).

Regarding claims 7 and 8, Sheu *et al.,* teach that the intermediate solution comprises an organic solvent such as ethanol (see page 2, [0015] and [0016]).

Regarding claims 12 and 13, Sheu *et al.,* teach that the nucleic acid is selected from a group consisting of natural (ie., human white blood cell DNA) and synthetic nucleic acid (ie., 800 bp PCR product) wherein the synthetic nucleic add is nucleic acid fragment (ie., 800 bp PCR product) (see page 2, [0013] to [0016]).

Regarding claim 15, Sheu *et al.,* teach labeling solid article or substance (ie., plastic films) with the third mixture containing said nucleic acid and drying the labeled solid article or substance (see page 2, [0015] and [0016]).

Therefore, Sheu *et al.*, teach all limitations recited in claims 1-5, 7, 8, 10, 12, 13, and 15.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheu *et al.*, as applied to claims 1-5, 7, 8, 10, 12, 13, and 15 above, and further in view of Mark (US Patent No. 4,258, 174, published on March 24, 1981).

The teachings of Sheu *et al.*, have been summarized previously, *supra.*

Sheu *et al.*, do not disclose that the organic solvent is benzole solvent such as toluene or xylene as recited in claim 6.

Mark teaches that inert organic solvents such as chloroform, toluene, and xylene are used to dissolve polycarbonate (column 4, lines 3-11).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 6 wherein the organic solvent is benzole solvent such as toluene or xylene in view of the prior art of Sheu *et al.,* and Mark. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of inert organic solvent (ie., chloroform taught by Sheu *et al.,*) from another kind of inert organic solvent (ie., toluene or xylene taught by Mark) during the process of performing the method recited in claim 6, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the inert organic solvent taught by Sheu *et al.,* (ie., chloroform) and inert organic solvent taught by Mark (ie., toluene or xylene) are used for the same purpose (ie., dissolving polycarbonate) and exchangeable (see Mark's patent, column 4, lines 3-11).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheu *et al.*, as applied to claims 1-5, 7, 8, 10, 12, 13, and 15 above, and further in view of Luciw *et al.*, (US Patent No. 4,876,089, published on October 24, 1989).

The teachings of Sheu *et al.*, have been summarized previously, *supra.*

Sheu *et al.*, do not disclose that the water-soluble solution is TE buffer as recited in claim 6.

Luciw *et al.*, teach that both water and TE buffer are used to dissolve DNA (column 12, first paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 11 wherein the water-soluble solution is TE buffer in view of the prior art of Sheu *et al.*, and Luciw *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of water-soluble solution from another kind of water-soluble solution (ie., TE buffer taught by Luciw *et al.*,) during the process of performing the method recited in claim 11, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the water-soluble solution taught by Sheu *et al.*, and water-soluble solution taught by Luciw *et al.*,are used for the same purpose (ie., dissolving DNA) and exchangeable (see Luciw *et al.*,, column 12, first paragraph).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

May 22, 2006

FRANK LU
PRIMARY EXAMINER